Complete Summary

GUIDELINE TITLE

Antibiotic prophylaxis in surgery. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Antibiotic prophylaxis in surgery. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2000. 36 p. (SIGN publication; no. 45). [150 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Surgical site infection

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Colon and Rectal Surgery
Infectious Diseases
Neurological Surgery
Obstetrics and Gynecology
Ophthalmology
Orthopedic Surgery
Otolaryngology
Surgery
Thoracic Surgery
Urology

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

1. To present evidence-based recommendations for antibiotic prophylaxis in surgery
2. To specifically address the following questions:
    - What are the risk factors for surgical site infection?
    - What are the benefits and risks of antibiotic prophylaxis?
    - For which operations is there evidence that prophylaxis reduces the risk of surgical site infection?
    - When and how should antibiotic prophylaxis be administered?
    - How many doses of prophylactic antibiotics should be administered?
    - What factors determine the cost-effectiveness of prophylaxis and how should these be used to formulate overall recommendations for prophylaxis?
    - What factors should be considered in the implementation and audit of local guidelines for surgical antibiotic prophylaxis?

TARGET POPULATION

- Patients undergoing elective operations in the clean, clean-contaminated or contaminated categories
- Patients undergoing emergency surgical procedures in the clean category and for emergency caesarean-section (a clean-contaminated operation)

Note: Patients undergoing emergency operations with contaminated or dirty wounds require antibiotic therapy rather than prophylaxis and as such are beyond the scope of the guideline.

INTERVENTIONS AND PRACTICES CONSIDERED

Intravenous prophylactic antibiotics

Note: The guideline does not cover administration of antibiotics by other routes (e.g., oral or intraincisional injection).

MAJOR OUTCOMES CONSIDERED

- Long-term and short-term morbidity
- Length of hospital stay

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were initially carried out on the Cochrane Library, Embase, HealthSTAR, and Medline from 1987 to 1998, and were updated during the course of development. In view of the volume of literature in this area, searches were initially restricted to existing guidelines, meta-analyses, and systematic reviews. Subsequently, searches for additional papers on audit of guideline effectiveness, and on the impact of haemodilution following intravenous administration of antibiotics were carried out. All search strategies were subject to independent review. Copies of the search strategies used are available from the SIGN Information Officer.

In the course of these searches it was noted that there is a high degree of inconsistency in the indexing of papers on antibiotic prophylaxis, with the terms â œAntibiotic prophylaxisâ or â œAntibiotics/therapeutic useâ apparently used interchangeably.

In addition to the initial search, members of the guideline development group searched the Medline database from 1960 to find the best evidence of the role of prophylactic antibiotics in surgical site infection prophylaxis. If a good meta-analysis was found this was used as the sole evidence. Failing this good quality randomised trials were sought. If there were one or two statistically sound randomized trials these are quoted as the sole evidence. Some of the references are old but these were used when they were judged to be â œpractice changingâ papers. In the absence of good randomised trials, other published evidence (e.g. other trials, audits, expert opinion etc.) was used as a guide to prophylaxis. For a lot of procedures both common (e.g. varicose veins and thyroid surgery) and more specialised (e.g. urethroplasty, Nesbit's operation) no evidence exists either for or against prophylaxis. Here common practice and referral to first principles act as a guide.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Statements of Evidence:

Ia: Evidence obtained from meta-analysis of randomized controlled trials.

Ib: Evidence obtained from at least one randomized controlled trial.

IIa: Evidence obtained from at least one well-designed controlled study without randomization.

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN website.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A: Requires at least one randomized controlled trial (RCT) as part of a body of literature of overall good quality and consistency addressing the specific recommendation (Evidence levels Ia, Ib).

Grade B: Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation (Evidence levels IIa, IIb, III).

Grade C: Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (Evidence level IV).

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

In section 6 of the original guideline document, the guideline developers review economic evaluations of surgical antibiotic prophylaxis. They outline the cost considerations related to surgical antibiotic prophylaxis, and they provide some "rules of thumb" that a decision-maker can use to estimate the likely cost-effectiveness of embarking upon a particular preventative strategy for surgical site infection.

Cost-effectiveness of Antibiotic Prophylaxis

Very few prospective randomised trials of surgical prophylaxis have included economic evaluation within the trial design. There are some evaluations that combine evidence of effectiveness of prophylaxis with estimates of the additional costs of treating wound infection. As described in section 4.1 of the original guideline document the effectiveness of prophylaxis can be estimated using an odds ratio for risk of wound infection. This, together with the rate of wound infection for that procedure in the hospital, is used to calculate the "numbers needed to treat" ([NNT], the number of patients that must receive prophylaxis in order to prevent one wound infection). Refer to the original guideline document for details.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

1. National open meeting discusses the draft recommendations of each guideline.
2. Independent expert referees review the guideline.
3. The Scottish Intercollegiate Guidelines Network (SIGN) Editorial Board reviews the guideline and summary of peer reviewers' comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The strength of recommendation grading (A-C) and level of evidence (Ia-IV) are defined at the end of the â œMajor Recommendationsâ field.

Principles of Antibiotic Prophylaxis

C: Inappropriate prolongation of surgical prophylaxis can be reduced by use of specific order forms for surgical prophylaxis, or recording of prophylaxis in single dose sections of existing drug prescription charts.

Administration of Intravenous Prophylactic Antibiotics

C: The antibiotics selected for prophylaxis must cover the common pathogens.

B: Patients with a history of anaphylaxis or urticaria or rash occurring immediately after penicillin therapy are at increased risk of immediate hypersensitivity to penicillins and should not receive prophylaxis with a beta-lactam antibiotic.

A: Prophylaxis should be started preoperatively in most circumstances, ideally within 30 minutes of the induction of anaesthesia.

A: Antibiotic prophylaxis should be administered immediately before or during a procedure.

B: An additional dose of prophylactic agent is not indicated in adults, unless there is blood loss of up to 1500 mL during surgery or haemodilution of up to 15 mL/kg.

Indications for Surgical Antibiotic Prophylaxis

Cardiothoracic Surgery

Antibiotic prophylaxis is recommended in:

A: Cardiac pacemaker insertion.

B: Open heart surgery, including coronary artery bypass grafting and prosthetic valve surgery.

A: Pulmonary resection.

Ear Nose and Throat Surgery

Antibiotic prophylaxis is recommended in:

A: Head and neck surgery (clean-contaminated/contaminated).

Antibiotic prophylaxis is not recommended in:

A: Ear surgery (clean).

C: Head and neck surgery (clean).

C: Nose or sinus surgery.

C: Tonsillectomy.

General Surgery

Antibiotic prophylaxis is highly recommended in:

A: Colorectal surgery.

Antibiotic prophylaxis is recommended but local policy makers may identify exceptions in:

A: Appendectomy or appendicectomy.

A: Biliary surgery (open).

C: Breast surgery.

C: Clean-contaminated procedures (extrapolated from specific clean-contaminated procedures).

A: Endoscopic gastrostomy.

A: Gastroduodenal surgery.

C: Oesophageal surgery.

C: Small bowel surgery.

C: Laparoscopic or non-laparoscopic hernia repair with mesh.

Antibiotic prophylaxis is not recommended in:

A: Laparoscopic or non-laparoscopic hernia surgery without mesh..

C: Laparoscopic cholecystectomy.

Neurosurgery

Antibiotic prophylaxis is recommended in:

A: Craniotomy.

A: Cerebral spinal fluid (CSF) shunt.

Obstetrics and Gynaecology

Antibiotic prophylaxis is recommended but local policy makers may identify exceptions in:

A: Caesarean section.

A: Hysterectomy (abdominal or vaginal).

A: Induced abortion.

Ophthalmology

Antibiotic prophylaxis is recommended but local policy makers may identify exceptions in:

C: Cataract surgery.

Orthopaedic Surgery

Antibiotic prophylaxis is highly recommended in:

A: Total hip replacement.*

B: Prosthetic knee joint replacement.*

Antibiotic prophylaxis is recommended in:

A: Closed fracture fixation.

A: Hip fracture repair.

A: Spinal surgery.

Antibiotic prophylaxis is recommended but local policy makers may identify exceptions in:

C: Insertion of prosthetic device* (extrapolated from trials of specific devices).

Antibiotic prophylaxis is not recommended in:

C: Orthopaedic surgery without prosthetic device (elective).

* Regardless of use of antibiotic cement.

Urology

Antibiotic prophylaxis is recommended in:

A: Transrectal prostate biopsy.

Antibiotic prophylaxis is recommended but local policy makers may identify exceptions in:

A: Shock-wave lithotripsy.

A: Transurethral resection of the prostate.

Antibiotic prophylaxis is not recommended in:

C: Transurethral resection of bladder tumours.

Vascular Surgery

Antibiotic prophylaxis is recommended in:

A: Lower limb amputation.

A: Vascular surgery (abdominal and lower limb).

Definitions:

Grades of Recommendations:

A. Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B. Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation. (Evidence levels IIa, IIb, III)
C. Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

Statements of Evidence:

Ia: Evidence obtained from meta-analysis of randomized controlled trials.

Ib: Evidence obtained from at least one randomized controlled trial.

IIa: Evidence obtained from at least one well-designed controlled study without randomization.

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The specific type of supporting evidence is explicitly identified in each section of the guideline.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate surgical antibiotic prophylaxis might:

- Reduce morbidity associated with surgical site infections
- Reduce hospital costs
- Reduce overall consumption of antibiotics
- Minimize rates of antibiotic resistance

The final decision regarding the benefits and risks of prophylaxis for an individual patient will depend on:

- The patient's risk of surgical site infection
- The potential severity of the consequences of surgical site infection
- The effectiveness of prophylaxis in that operation (see Section 4 of the original guideline document)
- The consequences of prophylaxis for that patient (e.g., increased risk of colitis)

POTENTIAL HARMS

Increase in number of cases of colitis caused by Clostridium difficile: The prevalence of Clostridium difficile infection is related to total antibiotic usage and, in particular, to the use of third generation cephalosporins. The consequences of Clostridium difficile include increased morbidity and mortality and prolonged hospital stay, leading to an overall increase in healthcare costs.

The final decision regarding the benefits and risks of prophylaxis for an individual patient will depend on:

- The patient's risk of surgical site infection
- The potential severity of the consequences of surgical site infection
- The effectiveness of prophylaxis in that operation (see Section 4 of the original guideline document)
- The consequences of prophylaxis for that patient (e.g., increased risk of colitis)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to changes as scientific knowledge and technology advance and patterns of care evolve.

These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available.

Significant departures from the national guideline as expressed in the local guideline should be fully documented and the reasons for the differences explained. Significant departures from the local guideline should be full documented in the patient's case notes at the time the relevant decision is taken.

This guideline is not intended to provide every surgical specialty with a comprehensive text on preventing surgical site infection (SSI), but rather to provide the evidence for current practice pertaining to antibiotic use, and to provide a framework for audit and economic evaluation.

The guideline does not cover the following types of surgery:

- Prevention of urinary tract or respiratory tract infections after elective surgery, with the exception of urinary tract infection after transurethral resection of the prostate

- Prevention of endocarditis after surgery or instrumentation (this is already covered by a UK guideline which is regularly updated)
- Use of antiseptics or topical antibiotics (e.g. tetracycline peritoneal lavage, subconjunctival injections for cataract surgery) for the prevention of wound infection after elective surgery
- Treatment of anticipated infection in patients undergoing emergency surgery for contaminated or dirty operations
- Administration of oral antibiotics for bowel preparation or to achieve selective decontamination of the gut
- Use of antibiotics for prophylaxis in patients with prosthetic implants undergoing dental surgery or other surgery that may cause bacteremia
- Transplant surgery

Nor does the guideline address choice of antibiotic. There is a huge quantity of trials comparing efficacy of different antibiotic regimens for prophylaxis.

Local antibiotic policy makers have the experience and information required to make recommendations about specific drug regimens based on an assessment of evidence, local information about microbiology and drug costs.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

It is expected that this Scottish Intercollegiate Guidelines Network (SIGN) guideline will act as a framework for local development or modification after discussion with clinicians and management. The Trust or Area Quality and Clinical Effectiveness Groups should be involved in conjunction with the Drug and Therapeutics, Antibiotic and Protocol development committees. Responsibility for prophylaxis in each unit should be clearly assigned. This guideline should ideally be used in conjunction with local guidelines for the management of postoperative pyrexia. Guideline implementation should be supported by a programme of continuing education.

See the original guideline document for information and recommendations on drug chart documentation of antibiotic administration and case record documentation and minimum data set.

Core Indicators for Audit

Process measures:

- Was prophylaxis given for an operation included in local guidelines?
- If prophylaxis was given for an operation not included in local guidelines, was a clinical justification for prophylaxis recorded in case notes?
- Was the first dose of prophylaxis given within 30 minutes of the start of surgery?
- Was the prescription written in the "once-only" section of the drug prescription chart?
- Was the duration of prophylaxis greater than 24 hours?

Outcome measures:

- Surgical Site Infection (SSI) rate = number of surgical site infections occurring postoperatively/total number of operative procedures.
- Rate of surgical site infections occurring postoperatively in patients who received inappropriate prophylaxis (as defined in the original guideline) compared with rate of this infection in patients who receive appropriate prophylaxis, expressed as a ratio.
- Rate of Clostridium difficile infections occurring postoperatively in patients who received inappropriate prophylaxis (as defined in the original guideline) compared with rate of this infection in patients who receive appropriate prophylaxis, expressed as a ratio.

See the original guideline document for the minimum data set for surgical antibiotic prophylaxis.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Antibiotic prophylaxis in surgery. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2000. 36 p. (SIGN publication; no. 45). [150 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jul

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr Dilip Nathwani (Chairman); Professor Peter Davey (Methodologist); Dr Peter Barton; Mr Derek Byrne; Dr Malachy Duffy; Dr Ian Gould; Mr Peter James; Dr Norman Lannigan; Dr Robert Masterton; Mr Eric Taylor

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline was issued in 2000 and will be reviewed in 2002 or sooner if new evidence becomes available.

Any amendments to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Antibiotic prophylaxis in surgery. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2000 Jul. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- Guideline 45: Supporting materials. There are two evidence tables -- Table 1 and Table 2 -- available in electronic form only from the SIGN Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- A background paper on the legal implications of guidelines. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on October 17, 2001. The information was verified by the guideline developer as of December 17, 2001.

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